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09/674,280	12/21/2000	Michinobu Nakamura	197748US0PCT	5123

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/14/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/674,280

Applicant(s)
Nakamura et al.

Examiner
Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 29, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

New claims 7-26 are pending and under examination. Claims 1-6 were canceled by applicants. [Paper No. 9 filed 10/29/2001].

Response to Arguments

Applicants' amendments and arguments filed 10/29/2001 have been fully considered but they are not persuasive for the reasons below.

Claim Rejections - 35 U.S.C. § 112

New claims 7-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite for the reasons similar to the reasons explained in the prior office action. The concept of "a liquid reaction system" remains indefinite the lack of clear definitions as disclosed and/or in the absence of particular limitations drawn to amounts of water as claimed. And, therefore, the criticality of the use of "a liquid reaction system" in the claimed method remains uncertain because no particular amounts of liquid or water are claimed. It is uncertain whether and how much of water is present during step 2 and step 3 in the method of claim 7, for example. And, further, it is uncertain as presently claimed what is "a fungal culture in a form of liquid koji" (see step 1 of the method of claim 7). Is it a drop or one ml of water with fungal spores? Is it 1L of water with a particular count of fungal fragments? A fungal culture *per se* is not a liquid. And it is uncertain how much of water or liquid is intended for a "liquid koji" which

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is a crude preparation of fungal culture such as some fungal mass suspension, semi-solid or semi-liquid fungal mass preparation. The idea of using 'a liquid reaction system' in the method as claimed is particularly uncertain when the method is limited since to the use of "submerged" culture tank (see new claims 11-13, 18, 20, for example). ~~xx~~

Claims 9 and 16 are indefinite because it is uncertain what criteria are intended for determining 10% to 60% of the total period of time as claimed. It is uncertain what is considered as "completion of the enzymatic hydrolysis" or what is a final product as intended. Thus, the metes and bounds of the claimed method can not be determined.

Claim Rejections - 35 U.S.C. § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 7-9, 11-13 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,045,819 [A] or WO 95/28853 [N].

The claims are directed to a method for producing hydrolyzed protein from vegetable material wherein the method comprises step of mixing a fungal culture with a vegetable material such as wheat gluten or de-fatted soybean, step of conducting first stage fermentation at temperature 15-39°C with aeration and step of conducting second stage fermentation at temperature 40-60°C. Some claims are further drawn to use of submerged culture or semi-liquid reaction culture.

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The cited references are relied upon as explained in the prior office action and repeated herein.

WO 95/28853 [N] discloses a method for producing hydrolyzed protein or a seasoning sauce (see abstract or see page 9, par. 2 and par. 4 or see page 11) wherein the method comprises step of mixing fungal culture such as koji mold *Aspergillus oryzae* with vegetable material such as wheat gluten, step of conducting first stage fermentation at temperature 30-35°C with aeration or mixing and step of conducting second stage fermentation at temperature 40-45°C. The cited method encompasses the use of liquid or submerged or semi-liquid reaction by teaching the use of liquefied gluten suspension or spore suspension (page 9, par. 2, line 3 or line 14). The cited reference suggests the use of defatted soybean (page 1, par. 1) in a method for producing hydrolyzed protein. The resulting product has a light color (abstract).

US 6,045,819 [A] discloses a method for producing hydrolyzed protein from vegetable material wherein the method comprises step of mixing a fungal culture such as various koji molds including *Aspergillus oryzae* (col.10, lines 30-39) with a vegetable material such as de-fatted soybeans (col. 9, lines 55-57), step of conducting first stage fermentation at temperature 28-30°C with aeration (col.9, line 60) and step of conducting second stage fermentation at temperature 30-60°C (col. 10, line 66) or 50°C (col. 11, line 56) or 58 °C (col. 12, line 2). The cited patent teaches the use of a liquid system for hydrolysis or addition of water into reaction system (col. 11, lines 66-67) or it teaches the use of at least some amount of water (col. 8, line 65) in a method for producing hydrolyzed protein. The cited method encompasses the use of pasteurization or

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sterilization of vegetable material prior to fermentation by teaching “cooking” or heating soybeans (Fig. 1). And the cited method encompasses pulverization of vegetable material prior to fermentation by teaching the use of soy powder or small granules (see col. 9, lines 11-20, for example). With regard to hydrolysis completion and/or hydrolysis time the cited patent teaches that these parameters are selected depending the type of particular koji mold used in the process (col. 14, lines 27-30).

The methods of the cited references are considered to anticipate the claimed method because the methods of the cited references comprise steps drawn to the use of two stage enzymatic hydrolysis of identical vegetable protein material with identical fungus which is a source of enzyme required for hydrolysis such as koji fungus or *Aspergillus oryzae* as the claimed method, wherein temperatures at each stages are identical to the claimed temperatures and wherein first stage is conducted with aeration of a culture system and the second stage is conducted without aeration as in the method of the present invention as claimed and as disclosed by applicants. The methods of the cited references encompass the use of a liquid culture system because the cited references clearly teaches the use of water at least during second stage which is performed without aeration.

Applicants’ main argument emphasizes the issues/limitations drawn to the use of a “liquid reaction system” and/or a “liquid koji”.

With regard to the method of US ‘819 (Takebe) applicants argue that the first stage in conducted to make a “preparation of the koji” rather than hydrolysis of vegetable material (see

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response page 7). This is not found convincing because identical vegetable material is used for the whole process, because koji culture is viable and contains the same enzyme and because the identical fungus is used during the whole process. Thus, the whole process, including the first stage whether it is “preparation of koji” or “enzymatic hydrolysis” using fungal culture which is viable “koji” culture inherently comprises enzymatic hydrolysis. The claimed method is not limited as claimed and it is not intended as disclosed to use a sterile or killed koji culture crude liquid preparation. And, further, the claimed method is not limited to any particular amounts of water for enzymatic hydrolysis as argued. The claimed “fungal culture in a form of liquid koji” which is required in the step 1 and which is drawn to inoculation of vegetable material with a koji fungus, is indefinite as claimed because this “form” does not indicate any amounts of fungal viable fragments/mycelium/spores for any amount of water/liquid carrier intended for viable inoculum. And the method of US ‘819 (Takebe) is either silent about the form of carrier which is used to deliver or to make koji inoculum. Or the cited method teaches that at least some amount of water such as 40% is present during first stage of enzymatic treatment of vegetable material. And the cited method clearly teaches the use of additional water for second stage at elevated temperature.

With regard to the method of cited patent WO 95/28853 (Muller) applicants argued that it is drawn to the use “solid” koji whereas the koji employed in the applicants’ method is a “liquid” koji (see response page 8). Yet, the claimed method is not limited to amounts of water. The Muller’s method is directed to production of a “seasoning sauce”. And “sauce” is a liquid but not a “solid” or powdered seasoning. The Muller’s method is directed to the use of “spore

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suspension” (page 9, par. 2, line 14). And the fact that Muller’s particular disclosure indicate steps of “mashing” and using bread cubes infected with fungus which are argued as being a protocol of a solid fermentation, does not exclude the use of some “submerged” culture system which is claimed in the applicants’ method. Moreover, the Muller’s vegetable material which is inoculated with a koji fungus is a solution (page 9, line 1) and it is a “hydrolyzate (eHVP)” which has a “marked liquefaction” (see page 9, lines 9-12) , and this vegetable material, which is liquid at least to some degree, is further subjected to two stage of fungal enzymatic hydrolysis. Therefore, the Muller’s method is reasonably expected to encompass the use of a least some “submerged” semi-liquid culture system“, if not a “liquid reaction system”, as it is required for the claimed invention.

Claim Rejections - 35 U.S.C. § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7-13 and 21-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,045,819 [A] or WO 95/28853 [N] in the light of US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al.[U] for the reasons similar to the reasons explained in the prior office action.

The claims 7-9, 11-13 and 21-24 as explained above. The claims 10, 25 and 26 are further drawn to amounts of reducing sugar such as 5% or less in the final product.

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The references US 6,045,819 [A] and WO 95/28853 [N] are relied upon as explained above for a disclosure of a method for producing hydrolyzed protein from vegetable material by using fungal cultures and two temperature stage fermentations. The cited methods are silent with regard to amounts of reducing sugars in a final product.

The references US 3,655,396 [B], JP 50019996 [O] and Muramatsu et al. [U] disclose methods for producing hydrolyzed protein from vegetable material by using koji molds and various fermentation temperatures such as 25-30°C {see abstract JP 50019996 [O]} or 33°C {see US 3,655,396 [B] example 3} or 50-60°C {see abstract Muramatsu et al.[U]} wherein the final amounts of reducing sugars in the resulting hydrolyzed protein are less than 5%. For example: 2.35% {see abstract JP 50019996 [O]} or 1.5% {see US 3,655,396 [B] example 3} or absent {see abstract Muramatsu et al.[U]}.

Therefore, the cited reference US 6,045,819 [A] and WO 95/28853 [N] are considered to anticipate the claimed invention since the cited methods of US 6,045,819 [A] or WO 95/28853 [N] comprise identical active steps and identical structural elements as the claimed methods. Thus, the final product at the completion of identical reactions would inherently be identical.

In the alternative, even if the claimed method is not identical to the referenced methods of US 6,045,819 [A] or WO 95/28853 [N] with regard to some unidentified steps or structural elements or some characteristics of fungal cultures, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced methods are likely to inherently produce the same or substantially similar products at the completion of

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reaction/fermentation particularly in the light of teaching of US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al.[U] which demonstrate that the use of koji mold preparation/fermentation at the same temperature from 25°C to up to 60°C or temperature either 25-30°C or 55-60°C are characterized by the same amounts of reducing sugars produced from vegetable materials such as less than 5% as the claimed resulting preparation. In addition, the cited US '819 teaches that hydrolysis of vegetable proteins depends on a particular type of koji mold which is employed for hydrolysis (col. 14, line 29). And the claimed invention appears to employ an identical koji mold such as *Aspergillus oryzae* (see specification page 24) as the cited methods. Thus the claimed method would have been obvious to those skilled in the art within the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of clear evidence to the contrary.

Applicants appear to argue that none of the references suggest the use of “liquid” system or koji. It is not found convincing as explained above. And it is not convincing as related to the references 3,655,396 [B], JP 50019996 [O] and Muramatsu et al.[U] because they either teach the use of “liquid” system or the criticality of “liquid” in the present invention is uncertain to patentably distinguish over the prior art because the final product which is disclosed have the same amounts of reducing sugars as claimed.

For example: the culture system of 3,655,396 [B] is liquid (see example 3, which teaches a “culture broth” at col. 5, line 74). The culture system of JP 50019996 [O] contains some water

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and the final product is characterized by “viscosity” (see English abstract). And Muramatsu et al.[U] teaches “filtrate” which is a liquid at least to some degree.

Applicants appears to argue that some unexpected results of the applicant’ method are related to a short period of fermentation. Yet, it is not claimed. And, further, at least some of the cited methods encompass an enzymatic hydrolysis within 48 hours or 65 hours, for example: see US ‘819 at col. 12, last line; see US ‘396 at col. 5, line 73; see abstract of JP 50019996.

The comparative example in the applicants’ specification is directed to a possession of a final hydrolyzed product which has a lower amount of reducing sugars as the result of practicing two stage fermentation when this two stage method is compared to one stage fermentation without aeration in a liquid system (table 1 and 2) rather than to a criticality of a “liquid” system/fungal culture which is argued. All cited methods are two stage fermentations with aeration at least during first stage wherein. And the final products are characterized by amounts of less than 5% of reduced sugars as explained above.

Claim Rejections - 35 U.S.C. § 103

Claims 7-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819 [A] or WO 95/28853 [N] in the light of US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al. [U] as applied to claims 7-13 and 21-26 above, and further in view of US 5,888,561 [C].

The claims 7-13 and 21-26 as explained above. The claims 14-20 are further drawn to pulverization and sterilization of vegetable material prior to fungal fermentation.

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The cited references are relied upon as explained above. The are not particularly clear with regard to pulverization and sterilization of vegetable material prior to fermentation.

The cited US 5,888,561 [C] clearly teaches the use of pulverization or extruding and sterilization of vegetable material prior to koji mold fermentation as a conventional procedure in the method for producing hydrolyzed proteins (example 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the cited methods of US 6,045,819 [A] or WO 95/28853 [N] by adding steps drawn to pulverization and sterilization of vegetable material prior to fermentation with a reasonable expectation of success in producing hydrolyzed proteins because pulverization and sterilization of vegetable material prior to fermentation are well known and conventional procedures in the methods for koji mold fermentations [C]. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

No arguments are of record with regard to criticality of pulverization and sterilization of vegetable material prior to fermentation.

No claims are allowed.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

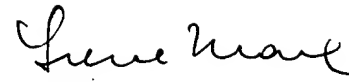
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Vera Afremova,

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January 11, 2001.

A handwritten signature in cursive script, appearing to read "Irene Marx".

IRENE MARX

PRIMARY EXAMINER

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Information Disclosure Statement

Applicants have requested to consider references cited in the International Search Report filed with Form 903. These references were received by PTO, placed in the application file and reviewed by Examiner together with all application papers. However, the information disclosure statement filed as a part of application papers (FORM 903) fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office on **PTO Form 1449**. Thus, references cited in the International Search Report have been placed in the instant application file, but the information referred to therein has not been officially considered.

If Applicants would like to have the list of these references be on a face of a printed patent document in the even of allowance, if any, they must be submitted on Form 1449 which allows special spaces for citations and examiner's initials.

V. Afnan